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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,396	12/18/2001	Kenneth W. Dobie	RTS-0339	5833

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EXAMINER	
SCHULTZ, JAMES	

ART UNIT	PAPER NUMBER
1635	9

DATE MAILED: 03/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/024,396	DOBIE, KENNETH W.	
	Examiner	Art Unit	
	J. Douglas Schultz	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-10 and 12-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-10 and 12-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Applicant's response filed February 20, 2002 has been considered. Applicants' amendment of claim 1 has been entered, and the request for reconsideration has been fully considered. Rejections and/or objections not reiterated from the previous office action mailed November 19, 2002 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

Response to Arguments

1. Claims 1-10 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Acton et al. (U.S. Patent Number 5,965,790), in view Calvo et al. and Baracchini et al. (U.S. Patent Number 5,801,154). These references are of record from the first Office action on the merits mailed June 5, 2002. Applicants correctly pointed out in their after final communication that the reference of Gimeno et al., cited in the previous Office action mailed November 19, 2002, was directed to regulators of applicants instant target, and not applicants' instant target. What follows is a new rejection made against Applicants amended claims submitted September 5, 2002 as drawn to SEQ ID NO: 3, said claims being re-submitted November 19, 2002. The

rejection that follows is necessitated solely based on Applicants amended claims submitted September 5, 2002. Arguments from applicants' response mailed September 5, 2002 that are considered relevant to the instant rejection are addressed below.

The claims are drawn to antisense compounds 8-50 nucleobases in length that target and inhibit the expression of CD36L1, and to internucleoside, sugar, or nucleobase modifications and chimeras of said antisense compounds, and compositions comprising said antisense compounds and pharmaceutically acceptable combinations.

Acton et al. teach isolated nucleic acids that target CD36L1 (SR-B1 of Acton et al.) and modify its expression. Acton et al. does not teach compositions comprising internucleoside, sugar, nucleobase, and 2' modifications, chimeras, and compositions providing for their *in vivo* use.

Calvo et al. teach the cDNA sequence encoding CD36L1, which is applicants' claimed target SEQ ID NO: 3.

Baracchini et al. teach making and using antisense oligonucleotides comprising sugar, nucleobase, 2' modifications, and chimeras, and compositions comprising said antisense compounds and pharmaceutically acceptable combinations. Baracchini et al. also teach that preferable targeting sites of mRNA transcripts include the 5'-untranslated region, the start codon region, the coding region, the stop codon region, and the 3'-untranslated region (cols. 9 and 10).

It would have been obvious to one of ordinary skill in the art to make antisense oligos to inhibit CD36L1, because Acton et al. expressly teach antisense inhibition of human CD36L1 which is substantially identical to the instant CD36L1 target sequence of SEQ ID NO: 3, which is taught by Calvo et al. It also would have been obvious to one of ordinary skill in the art to

incorporate modifications as taught by Baracchini et al. into antisense compounds, because Baracchini et al. teach that such modifications increase an antisense compound's cellular uptake, target affinity and resistance to degradation.

One would have been motivated to make such antisense compounds because Acton et al. teach that CD36L1 is a receptor that mediates uptake of HDL and LDL cholesterol from the blood plasma, and because Acton et al. expressly teach antisense compounds targeted CD36L1, and since Baracchini et al. teach that introducing modifications to said antisense compounds would prolong the activity of such antisense compounds. One of ordinary skill in the art would also have been motivated to target the 5'-untranslated region, the start codon region, the coding region, the stop codon region, and the 3'-untranslated region of an mRNA transcript, because Baracchini et al. teach that these are preferred sites for targeting gene transcripts using antisense-mediated inhibition. Therefore, based on the prior art, one of ordinary skill in the art would have been motivated to make the instantly claimed antisense inhibitors to the CD36L1 target of SEQ ID NO: 3.

Finally, one would have a reasonable expectation of success given that antisense-mediated inhibition of CD36L1 was previously described by Acton et al., and since Baracchini et al. teach and exemplify such antisense mediated inhibition, and since the steps involved are routine to one of ordinary skill in the art. Furthermore, one of ordinary skill would have had a reasonable expectation of success in modifying such compounds to enhance the activity of antisense compounds as taught by Baracchini et al., because such steps are routinely performed by one of ordinary skill in the art.

Thus in the absence of evidence to the contrary, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Applicants' state that, when viewed alone, none of Acton et al., Calvo et al., or Baracchini et al. teach or suggest antisense compounds targeted to the specific regions of the CD36L1 transcript of SEQ ID NO: 3 as presently claimed. This argument is not agreed with. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). It is acknowledged that the references when viewed individually do not teach the presently claimed invention; however, the test for obviousness is what the combined teaching of the prior art would have suggested to those of ordinary skill in the art. As indicated above, one would have been motivated to make such compounds because Acton et al. expressly teach antisense inhibition of CD36L1 that is substantially identical to applicants' claimed CD36L1 target of SEQ ID NO: 3. It thus follows that one of ordinary skill in the art would have been motivated to make antisense molecules targeted to the instant CD36L1 target of SEQ ID NO: 3. Moreover, because Acton et al. teaches that antisense transcripts can be used to target CD36L1 family members, and because Baracchini et al. teach that synthesizing and using antisense oligos to inhibit transcripts of known sequence is routine to one of ordinary skill in the art, this combination also provides a reasonable expectation of success which render the invention of the claims above obvious under 35 U.S.C. § 103(a).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 703-308-9355. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

James Douglas Schultz, PhD
March 26, 2003